



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

## CHARTER

### NATIONAL TOXICOLOGY PROGRAM SPECIAL EMPHASIS PANEL

#### AUTHORITY

Authorized by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The National Toxicology Program Special Emphasis Panel (SEP) is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

#### OBJECTIVES AND SCOPE OF ACTIVITIES

The SEP will advise the National Toxicology Program (NTP, also referred to as "Program") and its specialized centers on agents of public health concern, new/revised toxicological test methods, or other issues. Individual panels will be formed to advise on an as needed basis in response to specific issues or areas to be considered.

#### DESCRIPTION OF DUTIES

The SEP will provide independent scientific peer review and conduct objective and scientifically rigorous evaluations through the formation and use of individual panels on an as needed basis that will provide opinions and recommendations that include, but are not limited to, the strength of the scientific evidence that exposure to an agent is a hazard for human health, the adequacy of new/revised toxicological test methods relative to current toxicological tests for assessing specific toxicities, or the validation status of test methods.

The SEP will advise the Program Director on agents of public health concern, new/revised toxicological test methods, or other issues.

The SEP will advise on the quality, reproducibility, and limitations of scientific findings; identify critical knowledge gaps and data needs; identify areas where improved or new test methods are needed; or advise on the design, conduct, and adequacy of validation studies for new/revised test methods.

#### AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The SEP will advise, assist, consult with and make recommendations to the Director, NTP.

#### SUPPORT

Management and support services will be provided by the Office of Liaison, Policy and Review, NTP, or the specific NTP Center.

### **ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS**

The estimated annual cost for operating the SEP, including compensation and travel expenses for members, but excluding staff support, is \$35,302. The estimated annual person-years of staff support required are 0.8, at an estimated annual cost of \$94,752.

### **DESIGNATED FEDERAL OFFICER**

The Director, NTP, will assign a full-time or permanent part-time NTP employee to serve as the Designated Federal Officer (DFO) of the SEP. In the event that the DFO cannot fulfill the assigned duties, one or more full-time or permanent part-time NTP employee will be assigned these duties on a temporary basis.

The DFO will approve all the meetings of the SEP, prepare and approve all meeting agendas, attend all SEP meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH or the Director, NTP.

### **ESTIMATED NUMBER AND FREQUENCY OF MEETINGS**

Meetings of the SEP will be held as necessary.

### **DURATION**

Continuing.

### **TERMINATION**

Unless renewed by appropriate action prior to its expiration, the Charter for the National Toxicology Program Special Emphasis Panel will expire two years from the date the charter is filed.

### **MEMBERSHIP AND DESIGNATION**

Members and Chairs shall be selected on an "as needed" basis in response to specific issues or areas to be considered. Members and Chairs will be selected from outstanding authorities knowledgeable in the various scientific disciplines pertinent to the specific issues or areas being considered. All non-Federal members serve as NIH Peer Review Consultants.

### **SUBCOMMITTEES**

No subcommittees will be formed under this SEP.

### **RECORDKEEPING**

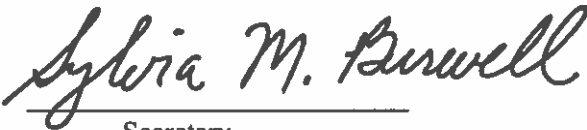
Meetings of the SEP will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. SEP records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

**FILING DATE**

January 7, 2017

**APPROVED:**DEC 07 2016

Date

A handwritten signature in black ink, reading "Sylvia M. Burwell". The signature is written in a cursive style with a large initial "S".Secretary